HONORABLE JUDGE THOMAS S. ZILLY

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

L.B. and M.B., on behalf of their minor child A.B., and on behalf of similarly situated others; L.B.; M.B., C.M. and A.H., on behalf of their minor child J.M., and on behalf of similarly situated others; C.M.; and A.H., Plaintiffs, vs. PREMERA BLUE CROSS, Defendant.	Case No. 2:23-cv-00953-TSZ **DEFENDANT PREMERA BLUE CROSS' REPLY IN SUPPORT OF MOTION TO EXCLUDE DR. DAN KARASIC UNDER *DAUBERT*** **NOTE ON MOTION CALENDAR: MARCH 14, 2025**

I. INTRODUCTION

The Court should grant Defendant Premera Blue Cross' Motion to Exclude Dr. Dan Karasic because his opinions are unreliable and do not meet the requirements of admissibility.

II. ARGUMENT

Plaintiffs admit the studies upon which Karasic relies are low-quality and contain unvalidated metrics, insufficient sample sizes, and insufficient follow-up periods. Karasic also relies on irrelevant studies of adults and non-surgical studies, fails to acknowledge the limited literature on gender surgery for minors, and cherry-picks studies to reach his conclusions. Karasic's opinions are not credible, would confuse the issues, and would not assist a trier of fact.

1. Karasic admits the evidence upon which he relies is low-quality.

Plaintiffs admit that Karasic's conclusions are based on limited, low quality evidence.

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First, Plaintiffs do not dispute that the World Professional Organization for Transgender Health ("WPATH") standards, upon which Karasic bases his conclusions, acknowledge there is no quality evidence supporting gender surgery for adolescents: "A key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments . . . the number of studies is still low, and there are few outcome studies that follow youth into adulthood." Dkt. 81-1;514–15.

Karasic acknowledged that the "number of studies is still low" and that there are "few outcome studies that follow youth into adulthood." Dkt. 111-8;9. The Cass Review examined multiple systematic reviews of the scientific evidence and likewise concluded there is very limited evidence to support medical interventions to treat gender dysphoria in minors. Dkt. 81-2;174–76; Dkt. 83;80–82.

Second, Plaintiffs do not dispute the Hayes independent literature review found the evidence supporting gender surgery for minors is "minimal" and "nonexistent." Dkt. 80;18; Dkt. 81-2;1–26; Dkt. 81-2;27–45. Plaintiffs claim the review did not incorporate enough studies but do not dispute Hayes' conclusions. Plaintiffs concede Karasic considered "the same body of research" as Hayes. Dkt. 130;12.

Third, Plaintiffs concede that the American Society of Plastic Surgeons ("ASPS") concluded "there is considerable uncertainty as to the long-term efficacy for the use of chest and genital surgical interventions for the treatment of adolescents with gender dysphoria, and the existing evidence base is viewed as low quality/low certainty." Dkt. 111-21; Dkt. 130;12.

Plaintiffs argue that Premera unreasonably demands randomized controlled clinical trials. This false. Premera has never stated that Plaintiffs must rely on a randomized controlled clinical trial, or that only high quality evidence (as compared to moderate) is sufficient. There are many types of reliable data other than randomized clinical trials, including prospective-long term follow up studies. Ex. 1,[1] Table 3. But there are no longitudinal studies with reliable design that adequately assess the long-term effects of gender-affirming surgery in minors. *See, e.g.*, Ex. 2.

[1] Exhibits are to the Consolidated Declaration of Gwendolyn Payton.

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What Plaintiffs cannot do is rely solely on evidence that is rated "low" or "very low" on the GRADE scale. Low-quality evidence means "confidence in the effect estimate is limited" and "the true effect may be substantially different from the estimate of the effect." Ex. 1, Table 2. The McMaster systematic review rated the data supporting mastectomies for minors and young adults as "very low" for certain outcomes, which means researchers "have very little confidence" in the study efficacy. Dkt. 81-3;5.

2. The Olson-Kennedy study that Karasic relied on contained an unvalidated outcome measure and is not reliable.

Plaintiffs concede Olson-Kennedy's 2018 study, which Karasic relied on, included an unvalidated "chest dysphoria" scale that only has "face" validity, which means it was only in the early stages of development. Dkt. 130;8; Dkt. 111-23. In other words, Olson-Kennedy's scale never reached the final stages of testing to see if it actually assessed what it was supposed to assess. The "chest dysphoria" scale asked subjective questions, such as "I have struggled to make future plans because of my chest," to determine participant subjective feelings. Dkt. 111-20;5, Table 1. Olson-Kennedy admits her chest dysphoria measure has only "face validity." Dkt. 111-12;21–22 (72:1-76:15), 37–39 (135:25-144:17).

Plaintiffs claim two other studies from 2021 and 2022 used Olson-Kennedy's chest dysphoria scale, which somehow validates it. Dkt. 130;8; Dkt. 133, Exs. 6,7. Not so. In fact, a 2022 editorial in JAMA Pediatrics, an international peer-reviewed pediatric journal made clear that Olson-Kennedy's "Chest Dysphoria Measure" has "not yet been validated for use." Dkt. 111-24. The JAMA Pediatrics statement directly undermines Plaintiffs' cited studies because it (1) post-dated the 2021 study Plaintiffs cite and (2) was included in the same periodical as Plaintiffs' 2022 study because the JAMA editorial board wanted to clarify that the scale was not validated. *Id.*

3. Karasic relies on studies with unreliably small sample sizes, insufficient follow up periods, and nonsurgical studies.

Plaintiffs do not dispute that the studies Karasic cites have participant sizes that are too small to be reliable. For example, the Mehringer study involved only 10 participants under 18.

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Dkt. 104;5. Plaintiffs claim that because the transgender population is "small," small sample sizes will always be a limitation. Dkt. 130;8. But Karasic himself claims to have seen "thousands of transgender patients," which undermines this representation.[2] Dkt. 111-5;3.

Plaintiffs also concede that all but one of the studies Karasic cites have follow up periods too short to gauge long-term outcomes: Mehringer (19 months); Olson-Kennedy (1.5 years); Tang (2.1 years). Dkt. 104;5. Plaintiffs again point to Olson-Kennedy's study for which the follow up ranged from "two to five years," but the research shows the average time to regret medicalized gender care is up to 10 years. Dkt. 130;9; Ex. 3.

Plaintiffs claim the follow-up period for these studies is comparable to mastectomy studies of cisgender minors, which Premera covers. Dkt. 130;9. This logic is flawed: Premera only covers gynecomastias for minors where there is a physical functional impairment, such as cancer. Dkt. 46-4; Dkt. 151;14. Gender dysphoria, by comparison, is a mental-health diagnosis. *Id.* Plaintiffs' attempt to conflate dissimilar diagnoses fails.

4. Karasic's methodology is unreliable.

Karasic's opinion is unreliable because he engaged in a results-driven methodology, cherry-picked literature that supports his position, and ignored literature that does not.

a. Karasic selectively relies on WPATH.

Karasic selectively relies on WPATH and ignores any authority to the contrary, despite acknowledging that WPATH itself concedes the evidence is limited and low quality for gender surgery for adolescents. Dkt. 111-8;9.

Plaintiffs do not dispute that the Ninth Circuit has rejected any claim that WPATH represents the standards for gender care, based on testimony from two of Premera's experts: Dr. Laidlaw and Dr. Levine. *See Doe v. Snyder*, 28 F.4th 103, 112 (9th Cir. 2022) ("Defendant proffered competing expert testimony that WPATH's Standards of Care are not universally endorsed and questioning whether there have been any high-quality studies showing that male

[2] Olson-Kennedy claims to have seen over 1,200 patients (Dkt. 111-9;3) and Brady claims to have seen over 1,000 transgender youth (Dkt. 111-13;5).

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chest reconstruction surgery is safe, effective, or optimal for treating gender dysphoria.").

Contrary to Plaintiffs' representations, ASPS explicitly "has not endorsed any organization's practice recommendations for the treatment of adolescents with gender dysphoria," including WPATH. Dkt. 111-21.

b. Karasic improperly relied on studies about adults.

Plaintiffs concede that several studies Karasic relied upon only involved adults. Dkt. 104;6. They argue, without support, that the age 18 "has no medical relevance" and that "age does not affect the efficacy of gender-affirming chest surgery" because it results in "fewer complications and revision procedures." Dkt. 130;9. This reveals a fundamental flaw with Plaintiffs' gender-care worldview: Karasic and Plaintiffs' other experts focus on postoperative physical complications while ignoring the importance of the longer-term mental health considerations.

Plaintiffs insist that studies of gender surgery in adults can directly inform whether to perform surgery on minors, despite admissions from Karasic and Plaintiffs' other experts that there are physical and psychological differences between adolescents and adults. Dkt. 111-8;25. Moreover, studies of adults are less applicable and reliable: under the GRADE approach, studies about a different age population suffer from "indirectness," which downgrades the reliability and applicability of the evidence when applied to a different age population. Ex. 1, Table 3.

c. Karasic improperly relies on non-surgical studies.

Plaintiffs concede Karasic relied on studies that were not about surgery at all. Plaintiffs have no explanation for why Karasic based his opinion on a study of hormones that did not assess surgery (for minors or otherwise). Karasic later admitted the study did not examine the effectiveness of gender surgery in minors. Dkt. 111-8;33–34 (121:16-122:1); Dkt. 104;7.

d. Plaintiffs ignore the Cass Review and other European studies while simultaneously acknowledging their relevance.

Plaintiffs claim the Cass Review and other European literature on gender-care are "irrelevant" to care in the U.S. Dkt. 130;10. But the Cass Review's literature review included U.S.-based studies, and Plaintiffs fail to explain why a comprehensive literature review on

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gender-care from another country is unreliable. Plaintiffs also claim the Cass Review is irrelevant because it does not address gender surgeries. *Id.*;12. They do not dispute, however, that the U.K. already limited gender surgeries to 18 and older, and the Cass Review did not recommend changes to that policy. Dkt. 83;285.

Plaintiffs' own experts agree the Cass Review is relevant and reliable, acknowledging that "certain aspects" "may have some applicability, including systematic reviews." Dkt. 111-8; 26–27 (91:25-94:5). And Plaintiffs' experts, including Karasic, agree the experience of gender-care providers globally is relevant to gender-care in the U.S. *Id.*; Dkt. 111-12;34 (122:22-123:6). Another court recently rejected Plaintiffs' criticisms of the Cass Review. Dkt. 149-3;53 n.13. The same is true here.

e. Plaintiffs misconstrue the RAND Review.

Plaintiffs selectively misquote the RAND Systematic Review, claiming it found a "clear evidence base" for mastectomies for adolescents. Dkt. 130;8. But the quoted language only compared mastectomies with other gender surgeries, including genital surgeries and implants, for which there is even less evidence than mastectomies. Dkt. 149-4;41. The RAND Review actually concluded that all mastectomy studies had "serious" risk of bias concerns and that "[a]ll outcomes were rated as having very low or low certainty of evidence." *Id.*;37,42.

5. Karasic's opinions on A.B. and J.M. are unreliable.

Karasic's medical necessity opinions on A.B. and J.M. are unreliable because he failed to consider their pre-existing conditions and surgical ambivalence.

Plaintiffs claim Karasic's sparse analysis of A.B. and J.M.'s pre-existing conditions is excusable because Premera only denied coverage based on age. Dkt. 130;12–13. Not so. There is ample evidence that Premera's Medical Directors reviewed every claim for gender surgery for minors on an individual basis, including to see whether there was evidence of functional impairment. Dkt. 149-2;147–48. This argument misses the bigger point: Premera has an age limitation for good reason, as evinced by both A.B. and J.M.'s individual cases.

Plaintiffs argue that Karasic's omission of A.B. and J.M.'s significant diagnoses only

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impacts the weight of his testimony, not admissibility. Plaintiffs are wrong: Karasic's refusal to consider pre-existing conditions render his opinion unreliable because those diagnoses are a crucial reason why A.B. and J.M.'s surgical claims were not medically necessary.

6. Karasic's opinion must be limited to rebuttal testimony.

Plaintiffs claim Karasic's opinion should not be limited to rebuttal testimony because his report was disclosed as a primary expert. Dkt. 130;13. This misses the point. Plaintiffs solely opposed Premera's cross-summary judgment motion on the grounds that the limitation constituted *facial* sex and age discrimination. Dkt. 99;37–41, 42. Plaintiffs represented that expert testimony is irrelevant because Premera's Medical Policy constitutes a categorical exclusion. Dkt. 44;19, n.10. Plaintiffs repeatedly claim the Court need not "make individual determinations, based on expert testimony, as to the medical necessity" in order to decide they win. Dkt. 55;3.

Because Plaintiffs insist experts have no bearing on their facial claims and have represented to this Court that they are not relying on those opinions in their dispositive motions, Plaintiffs can only offer experts for rebuttal purposes and not to support Plaintiffs' facial claims. *Wadler v. Bio-Rad Labs.*, No. 15-CV-02356-JCS, 2016 WL 6070530, at *3 (N.D. Cal. Oct. 17, 2016).

III. CONCLUSION

The Court should exclude the expert opinion of Dr. Karasic in its entirety.

DATED this 14th day of March, 2025.

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I certify that the foregoing contains 2,039 words, in compliance with the Local Civil Rules.

CERTIFICATE OF SERVICE

I certify that on the date indicated below I caused a copy of the foregoing document, DEFENDANT PREMERA BLUE CROSS' REPLY IN SUPPORT OF MOTION TO EXCLUDE DR. DAN KARASIC UNDER DAUBERT to be filed with the Clerk of the Court via the CM/ECF system. In accordance with their ECF registration agreement and the Court's rules, the Clerk of the Court will send e-mail notification of such filing to the following attorneys of record:

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